

REMARKS AND ARGUMENTS

This Amendment and Response is submitted in response to the Examiner's Office Action dated August 22, 2006. No claims are amended or cancelled by this paper. Accordingly, Claims 1-15 and 18 are pending in the current application. Reconsideration and withdrawal of the rejections of the claims are respectfully requested.

The Examiner has rejected Claims 1-15 and 18 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,478,316 to Bitdinger et al. (Bitdinger). Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bitdinger.

The present invention is directed to an injection device for the delivery of medicament to a patient through a retractable needle. The device includes an outer housing to contain the various components of the device and a movable inner housing. The inner housing is driven by an energy source. In a first mode the inner housing acts to drive the barrel and thus the needle forward against the biasing means. This accomplishes the injection by driving the needle out of the outer housing. In a second mode the inner housing acts to drive the plunger into the barrel, thus forcing the medicament out of the needle. In a third mode the inner housing acts to drive neither the barrel nor the plunger and remains in a position removed from the path of barrel and the plunger, allowing the barrel and needle to retract. Accordingly, each of these modes of operation are effected by the inner housing.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-15 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,478,316 to Bitdinger et al (Bitdinger). It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete

detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CCPA 1978); In re Kalm, 154 USPQ 10 (CCPA 1967). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 USPQ 2d 1566 (Fed. Cir. 1990). Applicant respectfully submits that the cited references do not teach all of the material elements and do not arrange the elements as required by the rejected claim language.

Bitdinger discloses a reloadable device for automatically injecting a dose of medicament. The device includes a sleeve that is operable to withdraw against the force of a spring into a housing upon the application of an external force, such as would occur by pressing the device against a body. This action causes the needle to be exposed for purposes of delivering the injection. The injection is achieved by a separate constant force spring that acts against a rod that is releasably coupled to a driver. Initially, the driver and rod remain coupled and together move a syringe assembly forward causing the needle to penetrate the skin. Thereafter, the driver releases from the rod and the rod acts on the piston portion of the syringe assembly to expel the medicament. The user then removes the needle and the sleeve moves forward under the action of the spring to again cover the needle.

Bitdinger does not disclose a device that contains a single component or element, under the influence of a single energy source, that in a first mode acts both on the barrel and the plunger of the syringe, in a second mode acts on only the plunger, and in a third mode acts on neither the barrel nor the plunger. The Examiner has equated the sleeve 28 of Bitdinger with the inner housing of the Claims 1 and 18, and housing 12 of Bitdinger with the outer housing of Claims 1 and 18. For the reasons set forth below, the sleeve 28 does not satisfy any of the three "modes" defined in Claims 1 and 18.

Regarding the first mode, the Examiner has cited the operation of the Bitdinger device as depicted in Figs. 5 and 6. As illustrated therein, a rearward force F is applied to the sleeve 28

when the device is pressed against the user's skin which disengages sleeve projection 28A from pushbutton 66. Next, the user has to manually depress the pushbutton 66 to cause "the syringe assembly 20 . . . to move forwardly and the needle thereof to penetrate the skin" [column 5, lines 60-66]. Notably, it is not the sleeve 28 (equated by the Examiner with the inner housing of the present invention) acting on the barrel 30 which causes the plunger 32 and barrel 30 to move axially. It is, in fact, the driver 58 and the rod 46 moving as a unit which moves the syringe forward. Neither the driver 58 nor the rod 46 is an "inner housing" as defined by Claims 1 and 18.

Regarding the second mode, the Examiner has cited the operation of the Bitdinger device as depicted in Fig 7. However, it can clearly be seen that it is not the sleeve 28 (equated by the Examiner to the inner housing of the present invention) which acts on the plunger 32 so as to expel medicament, but the rod 46. At this point in the injection, the sleeve 28 is retracted rearwardly and the rod 46 (disengaged from the driver 58) is moving forward to expel the medicament. In contrast, the claimed invention recites an inner housing which acts on the barrel and not the plunger to expel medicament.

Regarding the third mode, the Examiner has cited the operation of the Bitdinger device as depicted in Figs. 8, 10 and 11. Figs. 10 and 11 illustrate how a new syringe assembly can be mounted to the Bitdinger device, and not the final stage in an injection process. This is entirely irrelevant to the present invention, which is a single-use device which does not need to be reloaded. Fig. 8 depicts the sleeve 28 moving forward to cover the needle in the final stage of an injection. In contrast, the present invention recites a device including an inner housing that, in the final stage of an injection, acts on neither the plunger nor the barrel allowing the needle to retract backward inside of a separate outer housing. As can be seen, Fig. 8 of Bitdinger does not show the needle being retractable after injection. Instead of the needle retracting into the housing automatically, the user is required to pull the needle out of their skin themselves. As the user pulls the device away from his skin, the spring-biased sleeve 28 moves forward to cover the

needle as it is withdrawn from the skin. Notably, it is not the housing 12 (equated by the Examiner with the outer housing of the present invention) which covers the needle; it is the sleeve 28 (equated by the Examiner with the inner housing of the present invention). In contrast, the present invention recites a needle that retracts into and is covered by an outer housing. The Examiner is referred to column 2, lines 38-40 and column 6 lines 22-25 of Bitdinger for a discussion of the operation of the sleeve 28. In fact, it is not possible for the needle of the Bitdinger device to retract back into the housing. The tightly packed components (in particular, rod 46, plug 24 and sleeve 28) physically prevent the syringe 20 from being able to move rearwardly after an injection has been delivered. For this reason, Bitdinger provides a forwardly-moving sleeve 28 to cover the needle after injection

The Bitdinger reference does not contain each and every element set forth in the claims of the present application. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bitdinger. To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must show that 1) the references teach all of the elements of the claimed invention, 2) the references contain some teaching, suggestion or motivation to combine the references, and 3) the references suggest a reasonable expectation of success. See MPEP § 2142; see also, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); In re Kotzab, 217 F.3d 1365, 55 USPQ2d 1313 (Fed. Cir. 2000).

It is respectfully submitted that the Examiner has failed to provide a reference or combination of references that teach all of the elements of the claimed invention. Specifically, the Bitdinger references fails to disclose a device that contains a single component or element,

under the influence of a single energy source, that in a first mode acts both on the barrel and the plunger of the syringe, in a second mode acts on only the plunger, and in a third mode acts on neither the barrel nor the plunger. Additionally, Bitdinger fails to show a compressed gas energy source, and the Examiner does not cite to any reference disclosing a compressed gas energy source. In addition, the device disclosed by Bitdinger is so unrelated to the present invention that one of skill in the art would not look to the teachings of Bitdinger in considering the claimed invention. Therefore, for at least these reasons the rejection of Claim 9 as obvious over Bitdinger should be reconsidered and withdrawn.

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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